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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,131	02/14/2007	Wayne B. Harris	050508-1410	4639

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EXAMINER	
RAE, CHARLESWORTH E	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
04/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,131	HARRIS ET AL.	
	Examiner	Art Unit	
	CHARLESWORTH RAE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-33 are currently pending in this application and are the subject of the Office Action.

Restriction and Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of invention which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single species to which the claims must be restricted.

Group I. Claims 1-22, 27, and 30, drawn to a method of treating/preventing cancer or a tumour or a hypoxia related pathology. If this Group is elected, then the below Election of Species requirement is also required.

Group II. Claims 23-26, drawn to a pharmaceutical composition.

Group III. Claims 28-29, and 31-33, drawn to a method of modulating HIF-1 activity in a cell. If this Group is elected, then the below Election of Species requirement is also required.

The inventions represented above as Groups I-III relate to a general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they share the same or corresponding technical features. Specifically, the technical feature of Groups I-III is the HIF-I inhibitor compounds. The inventions lack unity, however, as the common technical feature is known in the art (WO 2004/087066 A2). Van Meir et al. (WO 2004/087066 A2) teach HIF-1 inhibitor compounds for treating cancer (page 1, lines 7-12; page 4, line 8 to page 11, line 7). Thus, the requirement is proper as the inventions represented above as Groups I-III lack unity of invention under PCT Rule 13.1.

Species Election regarding Groups I-III

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. For example, the generic inventions encompass multiple method of treatment species (treating or chemopreventive treatments), multiple compositions species comprising at least one HIF-1 inhibitor and/or one or more other optional agents (e.g. radiation and chemotherapy), which would reasonably exhibit different/variable therapeutic effects, depending of the specific chemical structure of the HIF-1 Inhibitor and/or the specific optional agent that is combined with said HIF-1 inhibitor. Thus, these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499,

applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Also, the application encompasses multiple hypoxia related pathologies, including different cancer species, which constitute distinct clinical conditions such that the therapeutic response achieved by administering a specific HIF-1 inhibitor for treating one cancer species may not be effective in treating a different cancer species.

Applicant is required to elect a single disclosed species from each of the below list as appropriate:

1a) a single disclosed completely chemically defined HIF-1 inhibitor compound species, wherein every variable/functional group is specifically defined (e.g. R1, R2, Ar1, Ar2 etc); or

1b) two or more completely chemically defined HIF-1 inhibitor compound species, wherein every variable/functional group is specifically defined (e.g. R1, R2, Ar1, Ar2 etc) for each HIF-1 inhibitor species.

Additional Species Election regarding Group I

As discussed above, this application contains claims directed to more than one species of the generic nvention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If applicant elects Group I, then applicant is further required to elect the following:

2) a single specifically disclosed disease species e.g. breast cancer;

3a) a treatment with an optional agent; or 3b) a treatment without an optional agent.

4) If applicant elects above item 3a, then applicant is further required to elect either 4a) an optional agent ; or 4b) chemotherapy.

5) If applicant elects above item 4b (i.e. chemotherapy), then applicant is further required to elect a specific chemotherapeutic agent(s) e.g. doxorubicin.

In addition, applicant is reuired to elect either 6a) a chemopreventatve treatment; or 6b) a non-chemopreventative treatment, for examination purposes.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to the additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after election, applicant must indicate which are readable upon the elected species (MPEP 809.02(a). Claims 1, 20, 23, 27, 28, 29, 30, and 31 are considered generic to the above species.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11 April 2008
/C. R./
Examiner, Art Unit 1611

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614